UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

ROSALIE JENSEN, Plaintiff, v. AMERICAN MEDICAL SYSTEMS, INC. Defendant.	No. 2:20-CV-00072-SAB **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

Before the Court is Defendant's Motion for Summary Judgment, ECF No. 35. A videoconference was held on October 22, 2020. Plaintiff was represented by Jeffrey L. Haberman and Peter J. Mullenix, who participated by videoconference. Defendant was represented by Whitney L. Mayer, who participated by videoconference, and Anne M. Talcott, who participated by telephone.

Plaintiff initially filed her Complaint in the Southern District of West Virginia as part of the Multi-District Litigation proceedings, *In Re: American Medical Systems, Inc. Pelvic Repair System Products Liability Litigation, MDL 2325*. ECF No. 1. Plaintiff asserts she was implanted with three of Defendant's products: Apogee; Perigee; and the Monarc Subfacial Hammock. *Id.* She is alleging sixteen counts, including (Ct. I) Negligence; (Ct. II) Strict Liability – Design Defect; (Ct. III) Strict Liability – Manufacturing Defect; (Ct. IV) Strict Liability – Failure to Warn; (Ct. V) Strict Liability – Defective Product; (Ct. VI) Breach of Express Warranty; (Ct. VII) Breach of Implied Warranty; (Ct. VIII)

Fraudulent Concealment; (Ct. IX) Constructive Fraud; (Ct. X) Discovery Rule, Tolling and Fraudulent Concealment; (Ct. XI) Negligent Misrepresentation; (Ct. XII) Negligent Infliction of Emotional Distress; (Ct. XIII) Violation of Consumer Protection Law; (Ct. XIV) Gross Negligence; (Ct. XVII) Punitive Damages.

Defendant now moves for summary judgment on Plaintiff's Strict Liability – Failure to Warn claim (Ct. IV) and Strict Liability – Manufacturing Defect claim (Ct. III). In her response, Plaintiff stated that she does not intend to pursue a separate claim for "manufacturing defect" as the claim has been construed in the MDL proceedings. ECF No. 38. Based on this representation, the Court will grant Defendant's Motion for Summary Judgment with respect to Ct. III, Strict Liability – Manufacturing Defect.

Motion Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). There is no genuine issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The moving party has the initial burden of showing the absence of a genuine issue of fact for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party meets its initial burden, the non-moving party must go beyond the pleadings and "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 248.

In addition to showing there are no questions of material fact, the moving party must also show it is entitled to judgment as a matter of law. *Smith v. Univ. of Wash. Law Sch.*, 233 F.3d 1188, 1193 (9th Cir. 2000). The moving party is entitled to judgment as a matter of law when the non-moving party fails to make a sufficient showing on an essential element of a claim on which the non-moving party has the burden of proof. *Celotex*, 477 U.S. at 323. The non-moving party

cannot rely on conclusory allegations alone to create an issue of material fact. *Hansen v. United States*, 7 F.3d 137, 138 (9th Cir. 1993).

When considering a motion for summary judgment, a court may neither weigh the evidence nor assess credibility; instead, "the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255.

Background Facts

On January 23, 2009, Dr. Renee L. Woods implanted Plaintiff with Defendant's Perigee, Monarc, and Apogee pelvic mesh devices at Lake Chelan Community Hospital in Chelan, Washington. Plaintiff asserts the implants caused her sexual discomfort, stress incontinence, urinary problems, and mesh erosion in her pelvic floor. ECF No. 9.

Washington Products Liability Act

Plaintiff's Failure to Warn claim falls under the Washington Products Liability Act (WPLA).[1] *Taylor v. Intuitive Surg., Inc.*, 187 Wash.2d 743, 754 (2017) ("The WPLA governs product-related harm claims based on a manufacturer's failure to warn."). Section 7.72.080 provides, in part:

> (1) A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.
>
> (b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate

[1] The parties agree that Washington substantive law applies to Plaintiff's Failure to Warn claim.

> and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.
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> (c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

Washington law follows the learned intermediary doctrine. *Taylor*, 187 Wash.2d at 757. Under this doctrine, while the manufacturer has a duty to warn patients of product risks, it can satisfy this duty by properly warning the doctor (the learned intermediary), who then takes on the responsibility of communicating those warnings to the patient. *Terhune v. A.H. Robins Co.*, 90 Wash.2d 9, 17 (1978).

1. Adequacy of the Warnings

A manufacturer has a duty to provide warnings or instructions commensurate with its harm and the risk. *Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wash. App. 335, 345 (2005). Generally, the adequacy of a warning will be a question of fact. *Id.* at 343. However, a question of fact can be determined as a matter of law when reasonable minds can reach only one conclusion from the admissible evidence. *Id.* To determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert. *Id.* at 344. The trier of fact must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved using the device. *Id.*

A plaintiff is not required to establish the exact wording of the alternative warning. *Ayers by and through Ayers v. Johnson & Johnson Baby Prod. Co.*, 117

Wash.2d 747, 756 (1991). Requiring plaintiffs in failure to warn cases to establish the exact wording of an alternative warning would impose too onerous a burden. *Id.* The jury might agree that a certain type of warning should have been provided, but they might not agree among themselves as to exactly how that warning should have been worded. *Id.* The statute's requirement that "the manufacturer could have provided the warnings or instructions which the claimant would have been adequate" is satisfied if the plaintiff specifies the substance of the warning. *Id.*

Here, Plaintiff relies on the testimony of her urogynecology expert, Dr. Bruce Rosenzweig, who opines that the risks and complications associated with the Apogee, Perigee, and Monarc devices were known by AMS and should have been—but were not—relayed to the medical community. This is enough to defeat summary judgment on the question as to whether the warnings were adequate.

2. Proximate Cause

Under Washington law, "[i]n a products liability suit alleging inadequate warnings, the plaintiff must show that their injury was proximately caused by a product that was 'not reasonably safe because adequate warnings or instructions were not provided.'" *Ayers*, 117 Wash.2d at 752. To show proximate causation, the plaintiff must show both cause in fact and legal causation. *Id.* (citation omitted). "Cause in fact refers to the actual connection between the act and an injury—but for the act, the injury would not have occurred." *Sherman v. Pfizer, Inc.*, 8 Wash. App. 686, 687 (2019). Legal causation depends on considerations of "logic, common sense, justice, policy, and precedent." *Ayers*, 117 Wash.2d. at 756. (quotation omitted). It involves the "determination of whether liability should attach as a matter of law given the existence of cause in fact." *Id.* (quotation omitted).

Cause in fact is generally a question for the jury. *Baughn v. Honda Motor Co., Ltd.*, 107 Wash.2d 127, 142 (1986). When the facts are undisputed, however, so that an inference can be made that is incapable of reasonable doubt or difference

of opinion, factual causation may be a question of law for the court. *Id.*

Defendant relies on the testimony of Dr. Woods, Plaintiff's physician who implanted the devices in question. Dr. Woods testified that she reviewed the Instructions for Use (IFU) before the surgery. The IFU was reviewed with her at her deposition. She testified she was aware of the risks, including the risks of vaginal surgery. When asked, Dr. Woods testified that at the time she made the decision to use the device, it was a good decision, so she stood by her decision to use the device.

Defendant argues that Dr. Woods' statement precludes Plaintiff from showing that a different, increased warning would have persuaded Dr. Woods to take a different course of action.

The Court disagrees with Defendant that Dr. Woods' statement permits the Court, rather than the jury, to determine proximate cause. First, Dr. Woods qualified her decision by stating that "*at the time*" she made the decision it was a good decision. A reasonable jury could conclude that she may have made a different decision regarding using Defendant's device, if she had been given additional warnings *at the time*. Dr. Woods' statement is not unequivocal or emphatic enough to take the proximate cause decision from the jury. Second, the Court agrees with Plaintiff that Dr. Woods is not necessarily an unbiased witness. Thus, it will be important for the jury to hear and evaluate her testimony on both direct and cross-examination and determine her credibility.

Because genuine issues of material fact regarding whether the warnings provided by Defendant were adequate and whether the failure to provide adequate warnings proximately caused Plaintiff's injuries, summary judgment on Plaintiff's failure to warn claim is not appropriate.

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Accordingly, **IT IS HEREBY ORDERED**:

1. Defendant's Motion for Summary Judgment, ECF No. 35, is **GRANTED**, in part; and **DENIED**, in part.

2. Plaintiff's Strict Liability – Manufacturing Defect Claim (Ct. III) is **DISMISSED**.

IT IS SO ORDERED. The Clerk of Court is directed to enter this Order and forward copies to counsel.

DATED this 26th day of October 2020.

Stanley A. Bastian
United States District Judge